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October 8, 1999

[Docket No. 98N-0313]

Dockets Management Branch (HFA-305)
Food and drug Administration
5630 Fishers Lane, rm. 1061,
Rockville, MD 20852
USA

Dear Sir,

Re: U.S. FDA Proposed Rule: Reclassification of Surgeon's and Patient Examination Gloves

We refer to the document "Federal Register/Vol 64, No 146 dated July 30, 1999/Proposed Rules and Notice" and would like to submit our written comments as followings:

1. Reclassification Surgeon's and Patient Examination Gloves into Class II Medical Devices.

Comment: We oppose the reclassification of Patient Examination Gloves into Class II. The patient examination gloves are manufactured in a mass production scale, which are intended for use as an effective mechanical barrier under non sterile condition. Moreover, the duration of use for patient examination gloves is comparatively shorter than the surgeon's gloves.

2. FDA recommends an upper limit of no more than 1,200 ug protein per NL glove, regardless of size, as the maximum level for NL powdered patient examination gloves.

Comment: The upper limit of no more than 1,200 ug per NL glove, REGARDLESS OF SIZE is very debatable. The current ASTM 5712-95 reports the protein level by ug (micro-gram) per gram of glove. Nonetheless, glove weight varies in between sizes. There is no data to show that the producers can manufacture all sizes of patient examination glove at 6 g, the basis of conversion taken by FDA. The upper limit should be objectively specified at ug per gram or ug per dm2 of glove.
The existing technology having difficulties to achieve this upper limit at 1,200 ug per glove for powdered glove. New technology has to be sought and this definitely affects the production cost and subsequently the cost of the product.

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3. FDA recommends a limit of no more than 2 mg powder per glove, regardless of size, as the recommended powder level for patient examination gloves to be labeled as "powder-free".

Comment: The limit 2 mg per glove is debatable. The variations of glove weights between sizes need to be considered. The limit should be specified at per gram of glove basis.

4. Expiration dating, to label shelf life from the date of manufacturing.

Comment: Currently, there is no established protocol for the shelf life studies, neither real-time nor accelerated ageing studies for parameters such as protein, powder and pin hole levels. In view of the debatable situation for protein and powder limits, such protocol has to be finalised after the objective limits are set.

Yours faithfully,

Yeoh Seng Guan
General Manager

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